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09/813,214	03/20/2001	Kenneth Tucker	7969-089-999	1989

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EXAMINER
SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
1645	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/813,214	Applicant(s) TUCKER ET AL.	
	Examiner Khatol S Shahnan-Shah	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/23/2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11-16,19,21,27,29,34,35,40 and 42-56* is/are pending in the application.

4a) Of the above claim(s) *13-16,27,29,35 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11-12,19,21,34 and 42-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

1. Applicants' Information Disclosure Statements, received 03/20/2001 paper number 8 is acknowledged. The information disclosure statement filed 03/20/2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because no application No., or filing date has been placed on the form. But in order to expedite prosecution since attorney docket number appears on the form the IDS has been considered as to the merits. The copies of the cited references AA-AY was located in the grandparent application No: 08/642,712 filed 05/03/1996. The IDS has been considered by the examiner, see attached form 1449.

Election/Restrictions

2. Applicants' response to restriction requirement and preliminary amendment of December 23, 2002, paper No. 10 is acknowledged. Claims 9, 10, 17, 18, 20, 22, 28, 33, 36, 37, 38, 39 and 41 were canceled without prejudice. Claims 7, 8, 11, 12, 19, 21, 27, 34 and 40 were amended. New claims 42-56 were added.

Applicants elected, with traverse to prosecute the subject matter of group directed to poly peptides in this application. Present claims 1-8, 11, 12 and 34 read on elected group I.

In response to species election applicants elected the species of claim 1 and 34.

The traversal is on the ground(s) that searching for groups III and IV will not put additional burden upon the office when searching for elected group I, has been noted. This is found persuasive. The examiner recombines groups I, III and IV, claims 1-8, 11-12, 19, 21, and 34, which are drawn to polypeptides. Newly added claims 42-56 also will be examined with recombined groups I, III and IV which read on polypeptides.

Claims 13-16, 27, 29, 35, 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions.

3. Currently claims 1-8, 11-16, 19, 21, 27, 29, 34,35, 40 and 42-56 are pending.

4. Claims 1-8, 11-12, 19, 21, 34 and 42-56 are under consideration.

Specification

5. The specification of the disclosure is objected to because: The use of the trademark ATCC has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. Correction is required. See MPEP § 608.01(b).

Double Patenting

6. Claims 1-8, 11-12, 19, 21, 34 and 42-56 of this application conflict with claims 1, 3, 4, 6-10, 12, 19, 21,27 and 33-56 of Application No. 08/642,712. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 5, 19 and 21 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 19, 21 and 27 of prior U.S. Patent No. 08/642,712. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-8, 11,12, 34 and 42-56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4, 6-10, 12, 19, 21, 27 and 33-56 of copending Application No. 08/642,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species and subgenera of the polypeptides claimed of the 08/642,712 anticipates the genus of the polypeptides in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 2, 6-8, 11-12, 19, 21, 42-47 and 52-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are now drawn to any isolated polypeptide of *Moraxella catarrhalis*, wherein said polypeptide is an outer membrane polypeptide of *Moraxella catarrhalis*, and has a molecular weight of about 180 kD to about 230 kD. The claims encompasses polypeptides whose molecular weight is determined by any means. The art provides for multiple means of determination of "apparent" molecular weight. These means are sodium dodecyl sulfate polyacrylamide gel electrophoresis with specific markers, actual molecular mass by means of calculation based on the weights of the sum total of individual amino acids present, the apparent molecular weight as determined by gel filtration chromatography. The identical protein as ascertained by these different methods will have different apparent molecular weights. Applicants specification has not provided molecular weight assessment by these other means. Applicants own specification indicates that the methods used to assess molecular weight provide for different determination of apparent molecular weight (see paragraphs end of page 17 and

beginning of page 18). As such, there is no conception of proteins having the claimed molecular weight wherein the assessment is made by means other than sodium dodecyl sulfate polyacrylamide gel electrophoresis using rabbit skeletal muscle myosin and *E.coli* β-galactosidase as the 200 kD and 116.25 kD molecular weight standards, respectively. The specification does not conceive any other means of identification or isolation of apparent molecular by any other means. As such, because these other means would lead to different apparent molecular weight determinations and moreover would include polypeptides not disclosed herein, the specification does not support the now recited genus claims.

10. Claims 19, 42-43, 46 -49 and 55-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antigenic polypeptide, does not reasonably provide enablement for a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/or use the invention commensurate in scope with these claims.

In the instant case claims 19, 42-43, 46 -49 and 55-56 are drawn to a vaccine. The only given example in the specification is in pages 28-29 mentioning the production of a *Moraxella catarrhalis* vaccine from inactivated or attenuated HA or NHA cultivars of *Moraxella catarrhalis.*

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated base on that limitation. See in re Vaeck, 947 F. 2d 488, 495,20 USPQ 2d 1438, 1444 (Fed Cir, 1991).

Dorland's Medical Dictionary (29th Edition, 2000) defines "vaccine" as "a suspension of attenuated or killed microorganisms (bacteria, viruses, or rickettsiae), or of antigenic proteins

derived from them, administered for the prevention, amelioration, or treatment of infectious diseases. In the instant case the applicants invention is not enabled for the prevention, amelioration, or treatment of infectious diseases. And one skilled in the art will not be able to make/and or use the invention without undue experimentation.

It's unclear from the specification exactly how the vaccine was produced or used. Additionally its unclear what type of immune response was elicited when the preparation was administered and whether or not the response correlated to protective immunity against *Moraxella catarrhalis.*

It is well known in the art that there are several different antigens from *Moraxella catarrhalis* (i.e. outer membrane proteins, lipooligosaccharides). It is also taught that since infections caused by *Moraxella* are predominately occur on mucosal surfaces, the mucosal immune response is likely important as the first line of defense. Mucosal or surface antigen immune response would likely be important in the search for candidate vaccine (Kyd et al. 2000). It has also been recognized in the art that there is currently no vaccine to prevent *Moraxella catarrhalis* infections because of a lack of good animal models for the diseases, a lack of information about the protective antigens, a lack of in vitro correlates to immunity against *Moraxella catarrhalis* in humans and the pathogenic mechanisms and host immune response to the pathogens has yet to be clarified (Chen, et al. 1996; Gu, et al. 1998, Hu et al. 2000; Samukawa, et al. 2000 and kyd, et al. 2000). While studies have shown the outer membrane proteins can elicit bactericidal antibodies, which promote bacterial clearance, the results have not lead to a predictable vaccine against infections caused by *Moraxella catarrhalis.* Clearly a great

amount of experimentation would be necessary in order to develop an efficacious vaccine against *Moraxella catarrhalis* infections.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the court of appeals in In re Wands, 8 USPQ 2d 1400 at 1404 (CAFC 1988).

These factors include 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the relative skill of those in the art, and 8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other antigens having claimed functional feature of capability of generating protective responses, 3) there are no working examples which suggest the desired results of a vaccine against *Moraxella catarrhalis*, 4) the nature of the invention involved the complex and incompletely understood area of protective immune responses against *Moraxella catarrhalis* , 5) the state of the prior art shows the lack of correlates to immunity with *Moraxella catarrhalis*, 6) the relative skill of those in the art is commonly recognized as quite high (post – doctoral level), and the lack of predictability in the field to which the invention pertains is recognized in the art as evidenced by the cited prior art.

In view of all of the above, in view of the lack of predictability in the art, it is determined that it would require undue experimentation to make and use the invention commensurate in

scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 1-8, 11-12, 19, 21, 34 and 42-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claims 1 and 34 is a relative term, which renders the claim indefinite. The term " substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 1 and 3 are indefinite from the use of the trademark ATCC. The use of the trademark ATCC has been noted in the claims of this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-6, 19, 21, 34 and 42, 44, 46, 48, 49, 51, 53-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Sasaki et al. (US 6,335,018, US 6,440,425, and US 6,440,424). All prior art of record applicants' exhibits A, B and C.

The claims are drawn to an isolated polypeptide of *Moraxella catarrhalis*, wherein said polypeptide is an outer membrane polypeptide of *Moraxella catarrhalis*, and has a molecular weight of about 180 kD to about 230 kD as determined by SDS-PAGE.

Sasaki et al. teach an isolated and purified polypeptide of *Moraxella catarrhalis*, wherein said polypeptide is an outer membrane polypeptide of *Moraxella catarrhalis*, and has a molecular weight of about 200 kD as determined by SDS-PAGE (see claim 1 of '081, '424 and '425). Sasaki et al. teach *Moraxella catarrhalis* ATCC 25240 (see '018 column 12, '425 column 16 and '424 column 12). Sasaki et al. teach an immunogenic composition comprising the poly peptide (for example see'081 columns 3-4 and example 5). Sasaki et al. teach vaccine, pharmaceutical acceptable carriers and adjuvants. (see columns 7-9 in all 3 references). Sasaki et al. also teach an isolated or substantially pure OMP polypeptide, which comprise 61.3% identity to SEQ ID NO: 10 (see '425 SEQ ID NO: 3, columns 46-56 and attached sequence alignment Acc# WO4505). The prior art anticipates the claimed invention. Limitations such as use of different strain of the organisms or stains are being viewed as limitations of optimizing experimental parameters.

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts

to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

March 27, 2003

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER